

OCT 20 2006

**510(K) SUMMARY**

**IRI™ INTEGRATED RETINAL IMAGER SYSTEM**

**510(k) Number K** 062295

**Applicant's Name:** MediVision Medical Imaging Ltd.

Tabor Building

Industrial Park P.O.Box 45

Yokneam Elit 20692

Israel

Tel: +972-4-9894884

Fax: +972-4-9894883

e-mail: david@medivision-ois.com

**Contact Person:** Ahava Stein/ Ofer Hornick

A. Stein – Regulatory Affairs Consulting

20 Hata'as St.

Kfar Saba 44425

Israel

Tel. + 972-9-7670002

Fax. +972-9-7668534

e-mail: [asteinra@netvision.net.il](mailto:asteinra@netvision.net.il) or [oh\\_asra@netvision.net.il](mailto:oh_asra@netvision.net.il)

**Date Prepared:** October 2006

**Trade Name:** IRI™ Integrated Retinal Image

**Classification Name:** CFR Classification section 886.1120 (Product code HKI)

CFR Classification section 892.2010 (Product code NFF)

CFR Classification section 892.2020 (Product code NFG)

**Classification:** Class II medical Device

- Predicate Device:** The IRI™ Integrated Retinal Imager device is substantially equivalent to a combination of the following predicate devices:
- TRC-NW200 (K041367) manufactured by Topcon. TRC-NW200 is a monocular ophthalmic non-mydratic camera system intended for capturing, displaying and storing images. When combined with the IMAGENet™ 2000 (a software program that is a class I medical product and is listed as such on the FDA's database), the device performs digital recording and image processing of the captured images, similar to the IRI™ Integrated Retinal Imager device.
  - VisuCam Lite (K021787) manufactured by Carl Zeiss. VisuCam Lite is an Ophthalmic Camera system, which is intended to photograph the fundus, similar to the IRI™ Integrated Retinal Imager device.
  - Canon CF-60DSi (k041546), manufactured by Canon Inc. The CF-60DSi is a digital fundus camera used for taking digital images of human eye without a mydratic, similar to the IRI™ Integrated Retinal Imager device.

**Device Description:** Medivision's IRI™ Integrated Retinal Imager System is a retinal camera, which is designed to perform digital fundus imaging. IRI™, as other fundus cameras, uses light photography to obtain clinical information. Using light sources (LEDs of different colours, a set of lenses and filters, and digital camera sensors, an image from the eye's retina is captured and later displayed for review. The device comprises a main console, a PC, a touch screen (as part of the main console) and a monitor. Digital image storage is available to several storage media.

**Intended Use / Indication for Use:** The IRI™ Integrated Retinal Imager System is a monocular retinal imager designed for routine use. The imager is suitable for documentation of findings in a clinical setting.

**Performance Standards:** None.

The design of the IRI™ Integrated Retinal Imager Cardiac Scanner System conforms to the following voluntary standards:

- IEC/EN-60601-1: Medical Electrical Equipment; Part 1: General Requirements for Safety. Second edition (1990), including amendments #1(1993), #2(1995), #13(1996).
- IEC/EN 60601-1-2: Medical Electrical Equipment; Part 1-2: Collateral Standard: Electromagnetic Compatibility- Requirements and Tests (2001)
- ISO 15004: 1997 Ophthalmic Instruments – Fundamental requirements and test methods.
- David Sliney et al.: Adjustment of guidelines for exposure of the eye to optical radiation from ocular instruments: statement from a task group of the International Commission on Non-Ionizing Radiation Protection (ICNIRP), Applied optics, Vol. 44, pp 2162-2176, 2005.
- ANSI/IESNA RP-27.1 -96 – Recommended practice for photobiological safety for lamps & lamp systems - General requirements.
- ANSI/IESNA RP-27.2-00 – Recommended practice for photobiological safety for lamps & lamp systems - Measurement techniques.
- ANSI/IESNA RP-27.3-96  
– Recommended practice  
for photobiological safety

for lamps and lamp  
systems - Risk group  
classification & Labeling.

**Test Data:** The IRI™ Integrated Retinal Imager System has been subjected to extensive safety, performance testing, and validation before release. Final testing of the IRI™ Integrated Retinal Imager System included various performance tests and software validation tests, designed to ensure that the device met all its functional specifications. Tests have been performed to ensure the device complies with industry and safety standards.

**Substantial Equivalence:** The IRI™ Integrated Retinal Imager System is similar to currently distributed retinal camera systems intended for fundus imaging applications. Similar to other predicate devices, the operating modes of the device include true color, fluorescein angiography, ICG angiography, red-free, red, blue and autofluorescence photography. The device uses LEDs as light sources instead of halogen and xenon lamps. Light energy outputs are within the limits set by ISO15004 and other standards for evaluating outputs of optical instruments (referenced above). Optical specifications are similar to those of predicate devices. Image processing and storage capabilities are similar to those of predicate devices. All of the above features are similar to these features in the predicate devices.

**Conclusions:** The conclusions drawn from the above Performance Testing and comparison to predicate devices is that the IRI™ Integrated Retinal

Imager device is substantially equivalent in safety and efficacy to the predicate devices listed above.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MediVision Medical Imaging Ltd.

c/o Ahava Stein

A. Stein Regulatory Affairs Consulting

OCT 20 2006

20 Hata'as St.

Kfar Saba 44425

Israel

Re: K062295

Trade/Device Name: IRI™ Integrated Retinal Imager System

Regulation Number: 21 CFR 886.1120

Regulation Name: Ophthalmic Camera

Regulatory Class: Class II

Product Code: HKI

Dated: October 10, 2006

Received: October 10, 2006

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

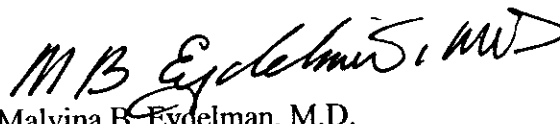
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "MB Eydelman, M.D.", with a stylized flourish at the end.

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose  
and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K062295

Device Name: IRI Integrated Retinal Imager System

Indications for Use:

The IRI Integrated Retinal Imager System is a monocular retinal imager designed for routine use. The imager is suitable for documentation of findings in a clinical setting.

Prescription Use ✓  
(Per 21 C.F.R. 801 Subpart D)  
C)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format Subpart

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 10/19/2006

(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number K062295